

Remarks:

Applicants have carefully studied the non-final Examiner's Action mailed 11/02/2005, having a shortened statutory period for response set to expire 02/02/2006, and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicants respond to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Priority

Applicants thank the Office for acknowledging the claim to priority.

Information Disclosure Statement

Applicants acknowledge that no IDS is filed with this application.

Drawings

The drawings stand objected to because the plug protruding from the internal organ is not depicted in the drawings as filed. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are filed herewith, attached to page 6 hereof.

Claim Rejections – 35 U.S.C. § 102

Claims 1-5 and 8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shaw. Reconsideration and withdrawal of this ground of rejection is requested for the reasons that follow.

The first distinction that must be recognized between the respective contributions of Applicants and Shaw is that Applicants' method is used where both an access channel and a biopsy tract are formed in a patient's tissue. The access channel extends through skin, fat, and other subcutaneous tissue but not an internal organ of the patient. The biopsy tract extends into an internal organ, terminating in a lesion that is biopsied. Of course, the access channel and the biopsy tract form a continuous bore in the patient's tissue but, again, the access channel does not extend into the internal organ.

Shaw discloses a tool and a method for plugging an access channel. Shaw neither discloses nor discusses biopsy tracts. Just as importantly, the method for plugging an access

channel as taught by Shaw does not teach or suggest the method disclosed by Applicants for plugging a biopsy tract.

At column 6, lines 25-29, Shaw recites:

Referring to FIGS. 1-1b, a device 2 according to the invention is shown for treating an access channel to the femoral artery after a catheterization (e.g. angioplasty) or similar procedure.

The leading end of the Shaw plug is positioned within an access channel so that said leading end is flush with a blood vessel, *i.e.*, so that the plug does not extend into the lumen of the blood vessel, thereby inhibiting blood flow.

As Shaw recites in column 6, lines 44-49:

...the plug is slid over the catheter body to position the distal end 26 of the plug so that it is adjacent the port 10 (FIG. 1b) and, hence, axially adjacent the vessel wall, but does not extend beyond the vessel wall into the vessel lumen.

The Shaw plug and method for using the plug thus teach away from Applicants' invention because Applicants' invention does not position the leading end of a plug in flush relation to a blood vessel so that said leading end does not protrude into the lumen of the blood vessel. Instead, Applicants' invention relates to an entirely different method. Applicants' invention relates to the plugging of a biopsy tract by selecting a plug having a preselected length, pushing the plug a first distance "a" so that the leading end of the plug is positioned at the end of an access channel and the beginning of a biopsy tract, and then continuing to push the plug a second distance that is equal to or less than the length of the plug so that a trailing end of the plug is flush with or protrudes slightly above the surface of the internal organ within which is formed the biopsy tract.

The measurements that are recited in Applicants' claims are performed, as the specification points out, by imaging devices such as CT, ultrasound, MRI, and the like. The prior art does not teach or suggest that the claimed measurements should be taken. It follows that the prior art does not teach or suggest the claimed measurements should be made with the aid of imaging devices such as CT, ultrasound, MRI, and the like. Applicant has therefore not limited the claims by reciting therein how the measurements are taken because any measurement means known to the art when the invention was made is within the scope of this invention. Moreover, as additional measuring means are developed in the future through incremental advances in

technology, such measuring means will also fall within the scope of these claims under the well-known *Hughes Aircraft* case. *Hughes Aircraft Co. v. United States*, 717 F.2d 1851 (Fed. Cir. 1983).

It should be understood that the "access channel" has a length "a" as defined by Applicants in their disclosure and is the distance from the surface of a patient's skin to the surface of an internal organ. It should be further understood that the biopsy tract in the internal organ begins at the innermost end of the access channel. Therefore, Applicants employ a plug that is equal or slightly greater in length than the length of the biopsy tract. Applicants push that plug through the access channel and into the biopsy tract until the leading end of the plug reaches the innermost end of the biopsy tract. The trailing end of the plug will therefore be flush with or will extend slightly beyond the surface of the internal organ within which the biopsy tract is formed. The leading end of Applicants' plug is not flush with a blood vessel wall at the end of an access channel as taught by Shaw. Thus it is understood that Applicants did not follow the teachings or suggestions of Shaw.

Claim 1 as filed was in condition for allowance because it recited a method neither taught nor suggested by Shaw. However, said claim is amended to point out the invention with an increased degree of particularity. However, as amended, the scope of the claim is the same as that of the unamended claim because the increased precision of the amended claim clarifies the invention without restricting it.

Regarding claim 2, said claim is in condition for allowance for the reasons just stated in connection with claim 1. Claim 2 recites a plug disposed in a biopsy tract, not an access channel, and further recites that the trailing end of said plug extends beyond the surface of the biopsied internal organ. In fairness to Applicant, Shaw neither teaches nor suggests such the method recited in claim 2. Nor is the claim subject to rejection just because it is broadly worded; said claim is neither taught nor suggested by the Shaw disclosure.

Regarding claim 3, element 92 of Shaw does not "help position the device for inserting the sealant plug so that a trailing end protrudes out of the surface of the biopsied organ" as contended by the Office. Shaw is silent and thus neither teaches nor suggests anything about the sealing of biopsy tracts. Again, the purpose of the Shaw disclosure is to teach how to align the leading end of a sealant plug with a blood vessel wall so that the sealant plug does not enter into the blood vessel lumen.

Regarding claim 4, many devices, including beakers, test tubes, measuring cups used to follow recipes, and so on, are provided with measuring marks. The provision of measuring marks on the Shaw device does not teach or suggest the use of measuring marks on a device that seals biopsy tracts as clearly claimed in claim 4.

Regarding claim 5, the Office cites column 20, lines 1-43 of Shaw to support the proposition that the Shaw system includes “a measuring system that configures the sealant plug blindly to a desired step...” As currently amended, claim 5 recites

A method for positioning a sealant plug in a biopsy tract of a biopsied internal organ, comprising the steps of using a measuring system supplied on an assembly configured to position the sealant plug blindly in said biopsy tract, to a desired depth through a coaxial needle such that a trailing end of said sealant plug is flush with or protrudes slightly beyond a surface of said biopsied internal organ.

The subject matter of claim 5, currently amended, is clearly unanticipated by Shaw.

Regarding claim 8, the Office contends that “the trail end of the sealant plug (element 94 in Figure 6C) is protruding beyond the surface of the ruptured internal organ (Figure 6C).” Applicants have therefore amended claim 8 to recite that the length of the trailing end that protrudes beyond the surface is in a range of about zero centimeters to about one-half a centimeter. Such range is neither taught nor suggested by Shaw. Figure 6C would impel one of ordinary skill away from the small amount of protrusion as taught by Applicants.

Claim 6 stands rejected under 35 USC 102(b) as being anticipated by Weinstein et al. (hereinafter referred to as “Weinstein”). Reconsideration and withdrawal of this ground of rejection is requested because the Office contends “...the measuring system of the current device can be viewed as the mesh 22 in Figure 4, which prevents the plug from going any deeper than is desired...” Applicants respectfully traverse such finding because Applicants’ measuring system is not disposed inside the body of the patient as is the mesh of Weinstein.

Claim Rejections – 35 USC § 103

Applicants acknowledge the quotation of 35 U.S.C. § 103(a).

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmidt in view of Desai; reconsideration and withdrawal of this ground of rejection is requested because the Schmidt device includes no locking device so in fairness to Applicant it cannot be said to

suggest a locking device. Schmidt, at claim 7 as cited by the Office, recites that hollow hub 16 of needle 12 engages head 20 of elongate sleeve 18 but such engagement is merely an insertion-limiting means, there being no locking function performed. See col. 2, lines 50-53. Moreover, the Schmidt device completely buries radioactive plugs in a prostate gland. No part of the radioactive plugs is flush with the prostate nor does any part thereof protrude from the surface of the prostate. Nor are the plugs inserted into a biopsy track – they are inserted into the gland by needle 14 which is an insertion needle and which performs no biopsy function. The Schmidt teachings clearly diverge from the invention recited in claim 7 as currently amended. Nor does this conclusion change when Schmidt is aggregated with Desai. As Desai discloses at column 15, lines 21-23, "...the depth of penetration of each first ends of each electrode into the soft tissue portion, can be precisely controlled by observing the indicator marks on the plunger." However, Desai, like Schmidt, neither teaches nor suggests a locking means as disclosed and claimed by Applicants. Both Schmidt and Desai lack a locking means and thus their aggregated teaching s and suggestions cannot include a locking means.

Prior Art

Applicants agree that the art made of record and not relied upon is not more pertinent to the claimed invention than the art cited.

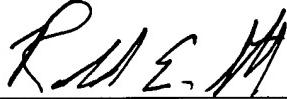
Conclusion

A Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicants' position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested. Applicants thank the Office for its careful examination of this important patent application.

Very respectfully,

SMITH & HOPEN

By:



Ronald E. Smith
USPTO Reg. 28,761
Suite 220
15950 Bay Vista Drive
Clearwater, FL 33760
(727) 507-8558
Attorneys for Applicants

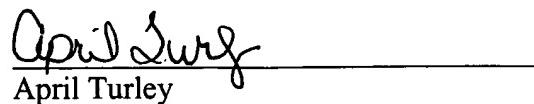
Dated: December 5, 2005

pc: John S. Fisher, M.D.
Mr. Frederick Ahari

CERTIFICATE OF MAILING
(37 C.F.R. 1.8)

I HEREBY CERTIFY that this correspondence is being mailed with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 5, 2005.

Date: December 5, 2005


April Turley

Mail Stop-Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Amendments to the Drawings:

The attached drawing pages include the following:

Replacement Sheets

Annotated Marked-up Drawings.

